

Application No. 09/147,036
Reply to Office Action of October 20, 2005
Amendment Dated January 20, 2006

REMARKS

Claims 1, 9-15, 19, 41, 43-53, and 55-58 were pending in this application. (Applicants note, however, that the Examiner has not referred to pending claim 58 in the October 20, 2005 Office Action, and thus, it is unclear whether or not the claim has been found allowable.) By this Amendment, Applicants have amended claim 41 for clarity. Support for the claim amendment can be found throughout the specification and claims as originally filed. This Amendment does not introduce any new matter and thus, its entry is respectfully requested. Upon entry of the present Amendment, claims 1, 9-15, 19, 41, 43-53, and 55-58 will remain pending and under examination.

The October 20, 2005 Office Action

Examiner's Rejections Under 35 U.S.C. §112, first paragraph-enablement

The Examiner rejected claims 41 and 43-53 under 35 U.S.C. §112, first paragraph, as lacking full enablement. Specifically, the Examiner has again confirmed that the specification is in fact enabling for a process for presenting passenger peptides or polypeptides on the surface of a gram-negative host bacteria, but has asserted that the specification does not enable a process for presenting a passenger peptide or polypeptide on the surfaces of all host bacteria wherein the passenger peptide or polypeptide is modified by glycosylation. The Examiner has thus concluded that practicing the invention as it is broadly claimed would require undue experimentation by one

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of ordinary skill in the art. The Examiner's full rationale is set forth at pages 2-5 of the Office Action.

In response, Applicants respectfully traverse the Examiner's rejection. The Examiner's rejection focuses on modification by glycosylation, as recited specifically in Applicants' claim 49. Essentially, the Examiner has based her position on the publications by Schäffer and Benz, which refer to glycosylation in certain bacteria. Applicants' claim 49, which depends from claim 46, refers to a passenger peptide or polypeptide which is chemically or enzymatically modified on the bacterial surface, wherein the modification is a glycosylation. This therefore means that the modification takes place after the surface display. (See, for example, page 29, lines 2-9 of the specification). It is therefore not necessary that all of the bacteria contain a natural glycosylation machinery to enable glycosylation of surface-exposed polypeptides on any bacteria. Any suitable state of the art method may be used. Benz and Schmitt, for example, describe glycosyl transferases (page 271, left-hand column, lines 11-12). Moreover, one of ordinary skill in the art will readily recognize that enzymatic glycosylation typically occurs at certain amino acid side chains (NH₂ and OH groups, specifically). Accordingly, in light of the above, Applicants believe the claims are fully enabled as currently presented. Thus, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 41, and 43-53 under 35 U.S.C. §112, first paragraph.

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Examiner's rejections under 35 U.S.C. §112, second paragraph

Claims 1, 9-15, 29 and 55-57

The Examiner rejected claims 1, 9-15, 29 and 55-57 under 35 U.S.C. §112, second paragraph as allegedly being indefinite. According to the Examiner, the terms “upstream” and “downstream” are not appropriate because the claims encompass circular plasmids, thus precluding the possibility of such orientation.

In response, Applicants respectfully traverse this ground of the Examiner's rejection. One of ordinary skill in the art would clearly recognize that the language employed in the rejected claims is fully appropriate. A circular vector (i.e., a plasmid) that encodes the defined polynucleotide, operatively linked to a promoter, would still contain a start sequence and thus, the coding orientation recited in the claims. Moreover, in an expression plasmid, only one of the strands is transcribed, such that “upstream” and “downstream” are clear with respect to the transcribed strand. Accordingly, the claim language needs no clarification and Applicants respectfully request reconsideration and withdrawal of this aspect of the Examiner's rejection.

Claims 41 and 43-53 (claim 49 in particular)

The Examiner rejected claims 41 and 43-53 (claim 49 in particular) under 35 U.S.C. §112, second paragraph as being indefinite in the recitation of “ . . . wherein the modification is a glycosylation . . . ” According to the Examiner, it is unclear where the peptide or polypeptide is glycosylated and at what point in the process the modification or glycosylation occurs.

In response, Applicants respectfully traverse this ground of the Examiner's rejection.

Applicants believe that the specificity the Examiner is requesting is not necessary to avoid indefiniteness. The specification at page 17, lines 3-9, for example, indicates that various modifications (covalent, non-covalent, glycosylation, phosphorylation, or proteolysis) are possible because of the surface presentation of the peptide. Moreover, as noted above, one of ordinary skill in the art will readily recognize that enzymatic glycosylation typically occurs at certain amino acid side chains (NH₂ and OH groups, specifically). Thus, one of ordinary skill in the art would recognize, based on this knowledge and the various teachings in the specification, that the claims as they are written are sufficiently clear to allow one to understand what is being claimed. Accordingly, Applicants respectfully request reconsideration and withdrawal of this ground of the Examiner's rejection.

Claims 41, 43-53 and 55-57

The Examiner rejected claims 41, 43-53 and 55-57, directed to a process for obtaining a library, as being indefinite under 35 U.S.C. §112, second paragraph, for the following additional reasons. According to the Examiner, it is unclear whether all peptides or polypeptides are expressed by the same vector, at the same time, or whether the process is repeated to generate multiple individual peptides and polypeptides.

In response, without conceding the correctness of the Examiner's position, but to expedite allowance of the subject application, Applicants have amended claim 41 for clarity. It is not entirely clear to Applicants precisely what the Examiner believes is indefinite about the claim, particularly in light of the final step of repeating the process to obtain the library. Nevertheless,

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Applicants have clarified the final clause of claim 41 to recite that steps a-g (as opposed to “the process”) are repeated. Applicants believe that this claim amendment obviates the Examiner’s rejection. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejection.

Finally, the Examiner rejected claims 41, 43-53 and 55-57 under 35 U.S.C. §112, second paragraph as being indefinite for reciting “. . . g) identifying and characterizing a binding partner for the surface-exposed passenger peptide or polypeptide . . .”

In response, Applicants respectfully disagree with the Examiner’s position. The specification describes, at page 11, lines 15-20, that surface presentation according to the invention renders the exposed passenger proteins freely accessible to binding partners. The specification provides a definition of “binding partner” at page 16, and further describes at page 19, lines 8-25, how such binding takes place between the passenger protein and a binding partner. Thus, we do not believe one of ordinary skill in the art would find the claims indefinite upon reading the specification, notwithstanding the Examiner’s contentions to the contrary. In any event, Applicants’ amendments to claim 41 should fully overcome this aspect of the Examiner’s rejection. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejections of claims 41, 43-53 and 55-57 under 35 U.S.C. §112, second paragraph.

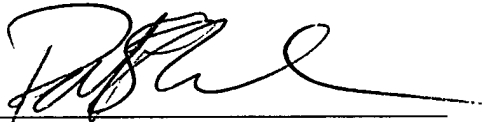
In view of the above remarks and amendments, Applicants believe that all of the Examiner’s rejections set forth in the October 20, 2005 Office Action have been fully overcome

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and that the present application is in condition for allowance. The Examiner is invited to telephone the undersigned if it is deemed to expedite allowance of the application.

No fee is believed due in connection with the filing of this Amendment. If, however, any fee is deemed necessary, authorization is hereby given to charge such fee, or credit any overpayment, to Deposit Account No. 02-2135.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'P. Skacel', written over a horizontal line.

Date: January 20, 2006

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